FDA 510(k) Premarket Notification

CLEARED

K030855 MODIFICATION TO ENDOVIVE INITIAL PLACEMENT PEG KIT, DIRECT PEJ KIT, PEG SAFETY KIT

Apr 17, 2003
30 days to decision

K030855 · Product code: **KNT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k030855/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Special
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Mar 18, 2003
Decision date	Apr 17, 2003
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corp**
Location	San Jose, CA, US
Contact	PAIGE SWEENEY
Website	https://www.bostonscientific.com/
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...